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CERTIFICATION AND ACCREDITATION INDUSTRY STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

# RB/T 161-2017

# Quality management system Health care equipment distribution service requirements

质量管理体系 保健器械经销服务 要求

**(English Translation)**

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## Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard is proposed and managed by the National Certification and Accreditation Administration.

The framework of this standard is consistent with GB/T 19001-2016 "Quality Management System Requirements".

This standard was drafted. Beijing World Standard Certification Center Co., Ltd., China Health Care Association Health Service and Research Committee, China Health Health Law Magazine, China Health Supervision Association, China Health Care Association Equipment Health Products Branch, China Medical Device Industry Association Medical Insurance Health Products Professional Committee, Beijing University of Traditional Chinese Medicine Wudang Medical Research Institute, Beijing Ruiqi Ning Biotechnology Co., Ltd., Beijing Zhongjianhui Health Management Co., Ltd., Heyiyuan (Beijing) Medical Research Institute, Beijing Oriental Desi Technology Co., Ltd., Hangzhou Haizi Commodity Co., Ltd., Guangdong Kasler Technology Development Co., Ltd., Jiangsu Longliqi Biotechnology Co., Ltd., Shandong Kangtai Industrial Co., Ltd.

## Introduction

With the increasing demand for health care equipment and the continuous development of the health care equipment industry, the types of health care equipment products are Increasingly, sales are also increasing year by year, but the development of China's health care equipment industry is not balanced, and there is competition and disorder in the health care equipment market.

The standards are vague, some operators are not standardized in their business practices,



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and they mislead consumers, even if they are entrusted by production plants, and have no licenses and illegal operations.

It has seriously affected the rapid and healthy development of the health care equipment industry. At the same time, there are fewer laws and regulations applicable to health care equipment in China, especially for There are fewer laws and regulations on health care device distribution services. The lack of national standards, industry standards and industry norms to enter the city the opportunity provided an opportunity to hinder the sustainable development of the healthcare device industry.

The purpose of this standard is to establish a unified, industry-specific and targeted quality management system in the health care equipment distribution service industry.

The system requires to guide and assist organizations engaged in health care equipment distribution services to establish a systematic, scientific, reasonable and operational Quality management system, implement continuous improvement, realize the management goal of distribution service, promote the standardized development of health care equipment distribution service industry, improve insurance the quality of health equipment distribution services truly provides customers with safe, effective, high quality and reliable products and services.

This standard is based on GB/T 19001-2016 "Quality Management System Requirements", combined with the characteristics and requirements of health care equipment distribution services.

Standardization is the basic principle for establishing a quality management system for the health care equipment distribution service industry.

This standard focuses on and adopts existing national standards, laws and regulations related to the health care equipment distribution service industry, and maintains coordination with it.

Sex and consistency. This standard sets out the specific requirements for the quality management system of health care equipment distribution service organization.

When this standard is used for certification purposes, it should be used together with GB/T 19001-2016 "Quality Management System Requirements" to constitute a health care device.

Distribution service organization quality management system certification basis.

Quality management system Health care equipment distribution service requirements

## 1 Scope

This standard specifies the requirements for the quality management system of health care equipment distribution service organization.



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This standard applies to the establishment, implementation, maintenance and improvement of its quality management system by the Health Care Equipment Distribution Service Organization (hereinafter referred to as the "Organization").

Can be used as a basis for the organization to implement self-evaluation and self-declaration, or as a basis for the organization's health care equipment distribution service quality management system.

Basis for evaluation and certification.

## 2 Normative references

The following documents are indispensable for the application of this standard. For dated references, only dated versions apply to this article.

Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 19000-2016 Quality Management System Foundation and Terminology GB/T 19001-2016 Quality Management System Requirements

## 3 Terms and definitions

The following terms and definitions defined in GB/T 19000-2016 apply to this document.

Health care equipment it has the functions of relieving fatigue, promoting health, preventing diseases, regulating body functions and other health functions, and does not aim at treating diseases.

**Note:** Health equipment includes massage equipment, health examination equipment, home physiotherapy equipment, rehabilitation equipment, fitness equipment, beauty and body care, drinking water care, air Purification class, etc., does not include medical equipment.

Health care equipment distribution service Organizing one or more processes for distributing health care devices, at least one of which must be provided between the organization and the customer.

**Note 1:** Health care equipment distribution services include procurement, distribution to distribution, storage, customer experience, sales, delivery tracking, after-sales service and other processes.

**Note 2:** Rewrite GB/T 19000-20163.7.7.

Customer experience the customer experiences the function and performance of the health care device through sensory, emotional, thinking, action, and association through direct observation or participation.



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## 4.1 Understanding the organization and its environment

### 4.1.1

The organization shall meet the requirements of 4.1 of GB/T 19001-2016.

### 4.1.2

The organization shall identify, monitor and review the factors in the internal and external environment. See Appendix A for the internal and external environment of the organization.



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